

REMARKS/ARGUMENT

Independent claim 22 has been amended to incorporate the limitation of now-cancelled claim 23, requiring that at least 90 vol % of the particles have diameters of greater than 10 μm . Accordingly, no new matter has been introduced.

Claims 22, 24-26, 30, 34-37, and 39-43 remain in the Application.

Claims 22-26, 30, 34-37, and 39-43 stand rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Babcock et al. US 2001/0053791 (Babcock). This rejection is respectfully traversed for the following reasons.

In response to previously submitted arguments, the Examiner states (at page 9 of the Final Rejection):

Applicant argues that as shown in Table 9 of the instant application, the Control C2 composition that is the same composition as Example 2 of Babcock, had an average particle diameter of 20 μm , which is one-half the minimum average particle diameter of 40 μm recited in independent claim 22.

This is not persuasive because the teaching of a prior art reference is not limited to the exemplified embodiments. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments.

The Examiner then continues:

Babcock teaches the solid amorphous dispersion particles in the range of from 1 to 200 μm , and encompassed within this range is the instantly claimed range of at least 40 μm . Babcock's disclosure of droplets that are less than about 20 to 50 μm in diameter also includes a droplet diameter of less than 40 μm , which meets the instantly claimed particle diameter limitation. Babcock teaches the components of the composition (the drug, the polymer, and the solvent), the particle size (1-200 μm), and the process by which the particles are prepared (preparing a solution of the drug and polymer in the solvent, spray-drying the solution). The average droplet diameter is a property that is inseparable from the droplets taught by Babcock. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable.

Amended claim 22 requires, *inter alia*, that "at least 90 vol % of said particles have diameters of greater than 10 μm ." In other words, claim 22 requires 10 vol % or less of the particles of the composition to have a diameter of less than 10 μm . This is not disclosed or suggested in Babcock. That this requirement results in a novel improvement in the claimed process is indicated at paragraph [0003] of the published application US 2004/0194338A1.

The inventors have found that the flow characteristics and collection efficiency of spray-dried dispersions can be improved by using a spray-drying apparatus equipped with atomizing means that produces droplets with an average droplet diameter of 50 μm or larger, with less than about 10 vol % of the droplets having a size less than 10 μm .

The compositions of Babcock were made using two-fluid nozzles, which result in a greater percentage of small particle sizes. The data in Table 9 of the instant application show that Control C2, which was made using the process of Babcock, resulted in 17 vol % of the particles having diameters of 10 μm or less, or nearly twice the claimed wt% of particles of that diameter. Thus, amended claim 22 is novel relative to Babcock. Since claims 24-26, 30, 34-37 and 39-43 all ultimately depend from claim 22, and so contain the same limitation, they are likewise novel relative Babcock.

For the reasons stated, early and favorable reconsideration is respectfully requested.

Respectfully submitted,



Dennis E. Stenzel

Reg. No. 28,763

Tel No.: (503) 227-5631